

APPLICATION NO.  
10/719,150

**FIRST NAMED INVENTOR**  
**Kevin J. Tracey**

**FILING DATE**  
**November 21, 2003**

**September 13, 2005**

**EXAMINER**  
**Not Yet Assigned**

CONFIRMATION NO.  
3380

**GROUP  
3754**

(Use several sheets if necessary)

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**EXAMINER**

DATE CONSIDERED

PTO-1449 REPRODUCED

**ATTORNEY DOCKET NO.**  
**3268.1000-012**

APPLICATION NO.  
10/719,150

## INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

**September 13, 2005**

(Use several sheets if necessary)

**FIRST NAMED INVENTOR**  
**Kevin J. Tracey**

**FILING DATE**  
**November 21, 2003**

**EXAMINER**  
**Not Yet Assigned**

CONFIRMATION NO. 3380	GROUP 3754
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## FOREIGN PATENT DOCUMENTS

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**EXAMINER**


DATE CONSIDERED

12/11/05

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  September 13, 2005  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. 10/719,150	
	FIRST NAMED INVENTOR Kevin J. Tracey		FILING DATE November 21, 2003	
	EXAMINER Not Yet Assigned		CONFIRMATION NO. 3380	GROUP 3754

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
W	C1	Sakamoto, R., <i>et al.</i> , "Inhibitory Effect of Glycyrrhizin on the Phosphorylation and DNA-Binding Abilities of High Mobility Group Proteins 1 and 2 <i>in Vitro</i> ," <i>Biol. Pharm. Bull.</i> 24(8):906-911 (2001).
	C2	Akamatsu, H., <i>et al.</i> , "Mechanism of Anti-Inflammatory Action of Glycyrrhizin: Effect on Neutrophil Functions Including Reactive Oxygen Species Generation," <i>Planta Med.</i> 57(2):119-121 (1991).
	C3	Azimov, M. M., <i>et al.</i> , "Pharmacological Study of the Anti-Inflammatory Agent Glyderinine," <i>Farmakol. Toksikol.</i> 51(4):90-93 (1988).
	C4	Lotze, M. T., and Tracey, K. J., "High-Mobility Group Box 1 Protein (HMGB1): Nuclear Weapon in the Immune Arsenal," <i>Nat. Rev. Immunol.</i> , 5:331-342 (2005)
↓	C4	Kuby, J., "Overview of the Immune System," In <i>Immunology</i> , (NY: W. H. Freeman and Company), page 1 (1992).

EXAMINER 	DATE CONSIDERED 12/1/05
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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. 10/719,150	
		FIRST NAMED INVENTOR Kevin J. Tracey		FILING DATE November 21, 2003	
		EXAMINER		CONFIRMATION NO. 3380	GROUP 3754
November 5, 2004 (Use several sheets if necessary)					

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
47	AS7	Romani, M., <i>et al.</i> , "Serological Analysis of Species Specificity in the High Mobility Group Chromosomal Proteins," <i>J. Biol. Chem.</i> , 254(8):2918-2922 (1979).

EXAMINER 	DATE CONSIDERED 12/11/05
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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. 10/719,150	
SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 23, 2004 (Use several sheets if necessary)				FILING DATE 11/21/2003	
				GROUP 3754	
		EXAMINER		CONFIRMATION NO. 3380	
		FIRST NAMED INVENTOR Kevin J. Tracey			

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
W	AD	5,594,114	01-14-1997	Goodearl, A. D. J., <i>et al.</i>

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
W	AQ	WO 2004/004763 A2	01-15-2004	Bianchi, M. E., <i>et al.</i>	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
W	AW5	Bustin, M., <i>et al.</i> , "Immunological Relatedness of High Mobility Group Chromosomal Proteins from Calf Thymus," <i>J. Biol. Chem.</i> , 253(5):1694-1699 (1978).
	AX5	Rauvala, H. and Pihlaskari, R., "Isolation and Some Characteristics of an Adhesive Factor of Brain That Enhances Neurite Outgrowth in Central Neurons," <i>J. Biol. Chem.</i> , 262(34):16625-16635 (1987).
	AY5	Daston, M. M. and Ratner, N., "Expression of P30, a Protein with Adhesive Properties, in Schwann Cells and Neurons of the Developing and Regenerating Peripheral Nerve," <i>J. Cell Biol.</i> , 112(6):1229-1239 (1991).
	AZ5	Parkkinen, J., <i>et al.</i> , "Amphoterin, the 30-kDa Protein in a Family of HMG1-type Polypeptides," <i>J. Biol. Chem.</i> , 268(26):19726-19738 (1993).
	AR6	Sobajima, J., <i>et al.</i> , "High Mobility Group (HMG) Non-Histone Chromosomal Proteins HMG1 and HMG2 are Significant Target Antigens of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies in Autoimmune Hepatitis," <i>Gut</i> , 44:867-873 (1999).
	AS6	Ma W., <i>et al.</i> , "Detection of Anti-Neutrophil Cytoplasmic Antibodies in MRL/Mp-lpr/lpr Mice and Analysis of Their Target Antigens," <i>Autoimmunity</i> , 32(4):281-291 (2000).
✓	AT6	Banks, G. C., <i>et al.</i> , "The HMG-I(Y) A-T-hook Peptide Motif Confers DNA-binding Specificity to a Structured Chimeric Protein," <i>J. Biol. Chem.</i> , 274(23):16536-16544 (1999).

EXAMINER <i>[Signature]</i>	DATE CONSIDERED 12/11/05
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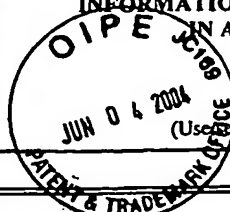
PTO-1449 REPRODUCED  SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION  September 23, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012  FIRST NAMED INVENTOR Kevin J. Tracey  EXAMINER	APPLICATION NO. 10/719,150  FILING DATE 11/21/2003  CONFIRMATION NO. 3380 GROUP 3754
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

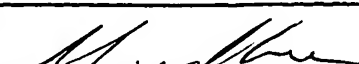
W	AU6	Scaffidi, P., <i>et al.</i> , "Release of Chromatin Protein HMGB1 by Necrotic Cells Triggers Inflammation," <i>Nature</i> , 418:191-195 (2002).
	AV6	Abaza, M.-S. I. and Atassi, M. Z., "Effects of Amino Acid Substitutions Outside an Antigenic Site on Protein Binding to Monoclonal Antibodies of Predetermined Specificity Obtained by Peptide Immunization: Demonstration with Region 94-100 (Antigenic Site 3) of Myoglobin," <i>J. Protein Chem.</i> , 11(5):433-444 (1992).
	AW6	Colman, P. M., "Effects of Amino Acid Sequence Changes on Antibody-Antigen Interactions," <i>Res. Immunol.</i> , 145(1):33-36 (1994).
	AX6	Freeman, B. D., <i>et al.</i> , "The Role of Inflammation in Sepsis and Septic Shock: A Meta-Analysis of Both Clinical and Preclinical Trials of Anti-Inflammatory Therapies," in <i>Inflammation: Basic Principles and Clinical Correlates</i> (John I. Gallin and Ralph Snyderman eds., Lippincott, Williams & Wilkins, Philadelphia, 3 <sup>rd</sup> ed. 1999), pp 965-975.
	AY6	Lederman, S., <i>et al.</i> , "A Single Amino Acid Substitution in a Common African Allele of the CD4 Molecule Ablates Binding of the Monoclonal Antibody OKT," <i>Mol. Immunol.</i> , 28(11):1171-1181 (1991).
	AZ6	Czura, C., <i>et al.</i> , "Dual Roles for HMGB1: DNA Binding and Cytokine," <i>J. Endotoxin Res.</i> , 7(4):315-321 (2001).
V	AR7	Wen, L., <i>et al.</i> , "A Human Placental cDNA Clone that Encodes Nonhistone Chromosomal Protein HMG-1," <i>Nucleic Acids Res.</i> , 17(3):1197-1213 (1989).

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. 10/719,150	
<b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b>  June 1, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Kevin J. Tracey		FILING DATE November 21, 2003	
		EXAMINER		CONFIRMATION NO. 3380	
				GROUP 3754	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

W	AT4	Passalacqua, M., <i>et al.</i> , "Stimulated Astrocytes Release High-Mobility Group 1 Protein, an Inducer of Lan-5 Neuroblastoma Cell Differentiation," <i>Neuroscience</i> , 82(4):1021-1028 (1998).
	AU4	Chou, D. K. H., <i>et al.</i> , "Identity of Nuclear High-Mobility-Group Protein, HMG-1, and Sulfoglucuronyl Carbohydrate-Binding Protein, SBP-1, in Brain," <i>J. Neurochem.</i> , 77:120-131 (2001).
	AV4	Imamura, T., <i>et al.</i> , "Interaction with p53 Enhances Binding of Cisplatin-Modified DNA by High Mobility Group 1 Protein," <i>J. Biol. Chem.</i> , 276(10):7534-7540 (2001).
	AW4	Ise, T., <i>et al.</i> , "Transcription Factor Y-Box Binding Protein 1 Binds Preferentially to Cisplatin-Modified DNA and Interacts With Proliferating Cell Nuclear Antigen," <i>Cancer Res.</i> , 59:342-346 (1999).
	AX4	Jung, F., <i>et al.</i> , "Antibodies Against a Peptide Sequence Located in the Linker Region of the HMG-1/2 Box Domains in Sera From Patients With Juvenile Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , 40(10):1803-1809 (1997).
	AY4	Bianchi, M. E., <i>et al.</i> , "Specific Recognition of Cruciform DNA by Nuclear Protein HMG1," <i>Science</i> , 243:1056-1059 (1989).
	AZ4	Suda, T., <i>et al.</i> , "A Novel Activity of HMG Domains: Promotion of the Triple-Stranded Complex Formation Between DNA Containing (GGA/TCC) <sub>11</sub> and d(GGA) <sub>11</sub> Oligonucleotides," <i>Nucleic Acids Res.</i> , 24(23):4733-4740 (1996).
	AR5	Ayer, L. M., <i>et al.</i> , "Antibodies to HMG Proteins in Patients With Drug-Induced Autoimmunity," <i>Arthritis Rheum.</i> , 37(1):98-103 (1994).
	AS5	Rauvala, H., <i>et al.</i> , "The Adhesive and Neurite-Promoting Molecule p30: Analysis of the Amino-Terminal Sequence and Production of Anti-peptide Antibodies That Detect p30 at the Surface of Neuroblastoma Cells and of Brain Neurons," <i>J. Cell Biol.</i> , 107(6):2293-2305 (1988).
	AT5	Sobajima, J., <i>et al.</i> , "Prevalence and Characterization of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies (P-ANCA) Directed Against HMG1 and HMG2 in Ulcerative Colitis (UC)," <i>Clin. Exp. Immunol.</i> , 111:402-407 (1998).
✓	AU5	Yamada, S., <i>et al.</i> , "High Mobility Group Protein 1 (HMGB1) Quantified by ELISA With a Monoclonal Antibody That Does Not Cross-React With HMGB2," <i>Clin. Chem.</i> , 49(9):1535-1537 (2003).

EXAMINER 	DATE CONSIDERED 12/11/05
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(Use several sheets if necessary)

APPLICATION NO.  
Continuation of 10/300,068

**APPLICANT**  
**Kevin J. Tracey and Haichao Wang**

FILING DATE

CONFIRMATION NO.

**GROUP**

## FOREIGN PATENT DOCUMENTS

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**EXAMINER**

DATE CONSIDERED

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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>October 30, 2003</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012	APPLICATION NO. Continuation of 10/300,068	
	APPLICANT Kevin J. Tracey and Haichao Wang		
	FILING DATE	CONFIRMATION NO.	GROUP

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
W	AR	Zhang, M. <i>et al.</i> , "Tumor Necrosis Factor", in <i>The Cytokine Handbook</i> , (Academic Press Limited), Third Edition, pp. 517-547 (1998).
	AS	Johns, E.W., <i>et al.</i> "History, Definitions and Problems", in <i>The HMG Chromosomal Problems</i> , (Academic Press), London: Chapter 1, pp. 1-7 (1982).
	AT	Landsman, D., <i>et al.</i> , "A Signature for the HMG-1 Box DNA-Binding Proteins", <i>BioEssays</i> , 15(8): 539-546 (1993).
	AU	Baxevanis, A.D., <i>et al.</i> , "The HMG-1 Box Protein Family: Classification and Functional Relationships", <i>Nucleic Acids Res.</i> , 23(9):1604-1613 (1995).
	AV	Merenmies, J., <i>et al.</i> , "30-kDa Heparin-Binding Protein of Brain(Amphoterin) Involved in Neurite Outgrowth", <i>J. Biol. Chem.</i> , 266(25): 16722-16729 (1991).
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	AX	Salmivirta, M., <i>et al.</i> , "Neurite Growth-Promoting Protein (Amphoterin, p 30) Binds Syndecan", <i>Exp. Cell Res.</i> , 200: 444-451 (1992).
	AY	Melloni, E., <i>et al.</i> , "Identity in Molecular Structure Between "Differentiation Enhancing Factor" of Murine Erythroleukemia Cells and the 30 kD Heparin-Binding Protein of Developing Rat Brain", <i>Biochem. Biophys. Res. Commun.</i> , 210(1): (1995).
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	AR2	Mohan, P.S., <i>et al.</i> , "Sulfoglycolipids Bind to Adhesive Protein Amphoterin (p30) in the Nervous System", <i>Biochem. Biophys. Res. Commun.</i> , 182(2)(1992).
	AS2	Yamawaki, M., <i>et al.</i> , "Generation and Characterization of Anti-Sulfoglucuronosyl Paragloboside Monoclonal Antibody NGR50 and Its Immunoreactivity with Peripheral Nerve", <i>J. Neurosci. Res.</i> , 44: 586-593 (1996).
↓	AT2	Vassalli, J., <i>et al.</i> , "The Plasminogen Activator/Plasmin System", <i>J. Clin. Invest.</i> , 88: 1067-1072 (1991).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
M	AU2	Parkkinen, J., <i>et al.</i> , "Interactions of Plasminogen and Tissue Plasminogen Activator (t-PA) with Amphoterin", <i>J. Biol. Chem.</i> , 266(25): 16730-16735 (1991).
	AV2	Redlitz, A., <i>et al.</i> , "Receptors for Plasminogen and t-PA: An Update", <i>Baillière's Clinical Haemtology</i> , 8(2): 313-327 (1995).
	AW2	Sobajima, J., <i>et al.</i> , "Novel Autoantigens of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies (P-ANCA) in Ulcerative Colitia: Non-histone Chromosomal Proteins, HMG1 and HMG2," <i>Clin. Exp. Immunol.</i> , 107:135-140 (1997).
	AX2	Sobajima, J., <i>et al.</i> , "Anti-Neutrophil Cytopasmic Antibodies (ANCA) in Ulcerative Colitis: Anti-Cathepsin G and a Novel Antibody Correlate With a Refractory Type," <i>Clin. Exp. Immunol.</i> , 105:120-124 (1996).
	AY2	Sparatore, B., <i>et al.</i> , "Extracellular High-mobility Group 1 Protein Is Essential for Murine Erythroleukaemia Cell Differentiation," <i>Biochem. J.</i> , 320:253-256 (1996).
	AZ2	Tomita, N., <i>et al.</i> , "Direct in Vivo Gene Introduction into Rat Kidney," <i>Biochem. Biophys. Res. Commun.</i> , 186(1):129-134 (1992).
	AR3	Wang, H., <i>et al.</i> , "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice," <i>Science</i> 285:248-251 (1999).
	AS3	Abraham, E., <i>et al.</i> , "Cutting Edge: HMG-1 as a Mediator of Acute Lung Inflammation," <i>J. Immunol.</i> , 165:2950-2954 (2000).
	AT3	Andersson, U., <i>et al.</i> , "High Mobility Group 1 Protein (HMG-1) Stimulates Proinflammatory Cytokine Synthesis in Human Monocytes," <i>J. Exp. Med.</i> , 192:565-570 (2000).
	AU3	Bianchi, M.E., <i>et al.</i> , "The DNA Binding Site of HMG1 Protein is Composed of Two Similar Segments (HMG Boxes), Both of Which Have Counterparts in Other Eukaryotic Regulatory Proteins," <i>EMBO J.</i> , 11(3): 1055-1063 (1992).
V	AV3	Bustin, M. "Revised Nomenclature for High Mobility Group (HMG) Chromosomal Proteins," <i>Trends Biochem. Sci.</i> , 26:152-153 (2001).

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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>October 30, 2003</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. Continuation of 10/300,068	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
W	AW3	Degryse, B., <i>et al.</i> , "The High Mobility Group (HMG) Boxes of the Nuclear Protein HMG1 Induce Chemotaxis and Cytoskeleton Reorganization in Rat Smooth Muscle Cells," <i>J. Cell Biol.</i> , 152:1197-1206 (2001).
	AX3	Wang, H., <i>et al.</i> , "Proinflammatory Cytokines (Tumor Necrosis Factor and Interleukin 1) Stimulate Release of High Mobility Group Protein-1 by Pituicytes," <i>Surgery</i> , 126:389-392(1999).
	AY3	Falciola, L., <i>et al.</i> , "High Mobility Group 1 Protein is Not Stably Associated with the Chromosomes of Somatic Cells," <i>J. Cell Biol.</i> , 137 (1):19-26 (1997).
	AZ3	Vanderbilt, J.N., <i>et al.</i> , "Monoclonal Antibodies as Probes for the Complexity, Phylogeny, and Chromatin Distribution of High Mobility Group Chromosomal Proteins 1 and 2," <i>J. Biol. Chem.</i> , 260(16):9336-9345 (1985).
	AR4	Bustin, M., <i>et al.</i> , "Antigenic Determinants of High Mobility Group Chromosomal Proteins 1 and 2," <i>Biochem.</i> , 21:6773-6777 (1982).
U	AS4	Tsuneoka, M., <i>et al.</i> , "Monoclonal Antibody Against Non-Histone Chromosomal Protein High Mobility Group 1 Co-Migrates With High Mobility Group 1 Into the Nucleus," <i>J. Biol. Chem.</i> , 261(4):1829-1834 (1986).

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